



Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Regulatory Directive

DIR2006-05

Requirements for Submitting Data Index, Documents and Forms

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1.0 Purpose

The purpose of this document is to communicate to industry and other interested parties, revisions to the requirements for submitting documents to Health Canada's Pest Management Regulatory Agency (PMRA) in support of applications to register or amend a pest control product registration, re-evaluation or special review.

These changes involve the format of the data index, the number of copies of documents and forms that must be submitted. It also communicates the requirement to use the most recent version of application related forms.

These revisions replace the corresponding requirements, where applicable, as detailed in Regulatory Proposal PRO2005-02, *Requirements for Submitting Data Index, Documents and Forms*, Regulatory Directive DIR2003-01, *Organizing and Formatting a Complete Submission for Pest Control Products*, and the Registration Handbook.

2.0 Background

The PMRA is committed to improving the efficiency of the pest control product registration process. Over the last several years, the PMRA has been building the electronic infrastructure to better manage applications for pest control product registrations, re-evaluations and special reviews.

Efficiency gained through electronic information management processes is key to the Agency's commitment to modernizing the registration system and in particular electronic delivery on the transparency requirements of the new *Pest Control Products Act* (PCPA 2002). The PCPA 2002 requires that the regulatory system be more transparent by allowing certain information including confidential test data (data), to be accessible to the public while protecting confidential business information (CBI). The PMRA will be leveraging its current electronic information management system to ensure timely and electronic delivery of information as required by the PCPA 2002. In addition, the electronic information management system will be facilitating the protection of CBI. The Agency's requirements for designating and segregating CBI are described in Regulatory Proposal PRO2005-03, *Confidential Business Information Designation and Segregation Part 1: Submission of Test Data*.

The currently required Portable Document Format (PDF) e-Index does not enable the PMRA to automate the loading of submitted documents to the Agency's electronic information management system, nor does it provide an electronic CBI indicator for each document submitted.

To address these gaps, the Agency is now requiring that e-indexes be prepared in the Extensible Markup Language (XML) format. XML is a format that allows for the sharing of information between different computers and different applications with different interfaces and data structures.

The PMRA has developed a stand alone software application that produces e-indexes in the XML format. The software application is called the e-Index Builder. In the move towards a fully electronic registration system, the PMRA has reached a point where only one copy of each submitted document and application related form is required.

In addition, the content of the application related forms has evolved, and the PMRA can no longer support use of older versions because they do not accommodate current information requirements.

2.1 What is the e-Index Builder?

The PMRA e-Index Builder is a stand alone software application that must be downloaded from the PMRA website and installed on a computer. It enables the user to create an XML e-index that fully describes each document submitted in support of an application to register or amend a pest control product registration, re-evaluation or special review, including responses to PMRA requests for information.

The PMRA e-Index Builder application facilitates the creation of an XML e-Index. It contains a pick list of Data Codes (DACO) and has built in functionality to allow for automated updates to the pick list. The pick list contains DACOs not only for confidential test data but also for other documents that may be required (e.g., cover letter, letter of confirmation of source of supply, etc.). The application also ensures that there is a CBI indicator for each document described in the e-Index.

The PMRA e-Index Builder also provides the ability to submit information in any of the approved data numbering systems: PMRA (DACO), OECD (IIA) and USEPA (OPPTS).

Detailed information and support for the PMRA e-Index Builder software application may be found in the *PMRA e-Index Builder User Guide*.

3.0 Scope

This policy applies to all instances where documents are submitted to the PMRA in support of the following:

- applications to register or amend a pest control product;
- re-evaluations;
- special reviews; and
- responses to deficiency requests or other requests for information.

4.0 Policy

4.1 Upon Publication of this Document

- Application related forms (application, fee and statement of product specifications)
 - Only one copy of a form is required (it may be submitted in paper or electronic format. If it is in electronic format, signatures must be incorporated and displayed in the PDF file.)
 - Only the most recent version of a form will be accepted, i.e., the one posted on the PMRA website at the time an application is being prepared.
- Only a single copy of each document being submitted is required. See Section 5.0 for the conditions under which an electronic or paper document will be accepted.
- All indexes submitted to the PMRA must be electronic and in the XML format, as generated by the e-Index Builder application, and must be accompanied by:
 - one paper* version; or
 - one electronic version of each document being submitted.

NOTE: Failure to comply with the revised requirements may delay the receipt and verification of an application.

Applicants are encouraged to begin designating and segregating CBI in the manner detailed in Regulatory Proposal PRO2005-03, *Confidential Business Information Designation and Segregation Part I: Submission of Test Data*.

5.0 Summary of Requirements

Requirement Schedule	e-Index Format	Data Format	CBI Document Identification
Mandatory as of publication of this directive.	XML	1 electronic copy OR 1 paper* copy	Ability to identify CBI documents.

*Efficacy and value data summaries must continue to be provided in electronic spreadsheet format (e.g., Excel, Lotus 123) and as per current requirements (e.g., REG2002-04, *Category C Submission Efficacy Review*; DIR2003-04, *Efficacy Guidelines for Plant Protection Products*, etc.).

6.0 Downloading, Installing and Using the PMRA e-Index Builder Software Application

Instructions for installing and using the e-Index Builder may be found in the *e-Index Builder User Guide*. This document also outlines the PMRA business rules for each of the fields of information (metadata) required to describe each document identified in the e-Index.

Requests for assistance, including requests for the technical definition for the PMRA e-Index XML format, should be directed to the PMRA via the Pest Management Information Service.

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